

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2271272	<b>(X3) Date Survey Completed</b>  04/04/2025
<b>Name of Provider or Supplier</b>  Wellave Dermatology Llc	<b>Street Address, City, State</b>  116 Defense Hwy #501, Annapolis, MD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3043</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: Based on patient log record review, surveyor observation, and interview with the histotechnician (HT), the laboratory failed to retain histopathology slides from Mohs surgery for at least 10 years from the date of examination. Findings: 1. The laboratory performs H&amp;E staining procedures to evaluate histopathology slides for Mohs surgery patients. Patients are logged onto a patient log by name and assigned a case number (#). The log entry also records the number of stages of the Mohs surgery, the number of blocks created from the tissue samples, and the total number of slides stained and reviewed by the doctor. 2. A random review of patient log records showed that case # "25-129" was performed in two stages, with two blocks, and that a total of three slides were stained and given to the doctor for interpretation. 3. During a review of the physical slides, it was observed that there were two slides labeled "S1" (stage one) for case # 25-129. There were no slides for stage two found at the time of the survey. 4. During an interview on 04/04/2025 at 11:55 AM, the HT confirmed that they were not able to locate one of the three slides that had been made and interpreted as part of case # 25-129.</p>
<b>D5473</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p>

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)  
(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on quality control (QC) and patient log record review and interview with the histotechnician (HT), the laboratory failed to ensure that daily stain QC was consistently documented, recording the quality of the staining characteristics of the Hematoxylin and Eosin (H&E) stain each day of patient testing. Findings: 1. The laboratory performs H&E staining procedures to evaluate histopathology slides for Mohs surgery patients. Daily stain QC for the H&E stain is recorded on the "Control Slide" log. 2. A review of daily stain QC logs from 01/15/2024 to 12/19/2024 showed that the results of the stain QC was not documented on the "Control Slide" log on 11/15/2024; and 3. A review of patient logs for the same time period showed that there were eight patients tested on 11/15/2024 ("Mohs case #" 24-532 through 24-539). 4. During an interview on 04/04/2025 at 11:00 AM, the HT confirmed that daily stain QC was not consistently documented.